

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: LATEX GLOVES PRODUCTS : MDL DOCKET NO. 1148
LIABILITY LITIGATION :
: ALL CASES

DAUBERT ORDER—MEMORANDUM

AND NOW, this 10th day of May, 2002, defendant manufacturers and distributors of latex gloves having moved *in limine* to exclude the Fed. R. Civ. P. 702 opinions¹ of plaintiffs' witnesses and hearings having been held on February 11 – 13, March 4 – 5, and April 22, 2002, the following Daubert rulings are entered:²

1. M. Eric Gershwin, M.D. – Dr. Gershwin, a board certified specialist in allergy, immunology, and internal medicine, is Professor of Medicine and Chief of the Division of Rheumatology/Allergy and Clinical Immunology at the University of California School of Medicine, Davis, California and is also Chairperson of the Graduate Group in Immunology. No objection was made to his qualifications.³

¹The opinions in question are generic and not case-specific.

²These general rulings will be supplemented with an adjudication as necessitated. The principles of law and the gatekeeping function of the trial judge are set forth in Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 113 S.Ct. 2786, 2795, 125 L.Ed.2d 469 (1993) (“trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable”). A non-exhaustive list of factors is discussed and analyzed.

³Defendants' three rebuttal witnesses: H. James Wedner, M.D., a specialist in allergy, immunology, and internal medicine, is Professor of Medicine and Director of the Allergy and Immunology Fellowship Training Program at Washington University School of Medicine, St. Louis, Missouri; Steven L. Kagen, M.D., a board certified specialist in allergy, immunology, and internal medicine, is Assistant Clinical Professor in the Division of Allergy and Clinical Immunology at the Medical College of Wisconsin, Milwaukee, Wisconsin; John A. Baron, M.D., a board certified specialist in internal medicine, is Professor of Medicine at Dartmouth Medical School and was Founding

Opinions 1 through 5⁴ – motion denied.

Opinion 6 (each and every exposure to NRL contributes to sensitization and allergy) – motion granted.⁵ However, the witness is not precluded from testifying to the foundations and reasons given for this opinion.

2. Charles H. Kyper – Mr. Kyper, president of Kyper & Associates, a medical device consulting firm, was employed at the FDA from 1966 to 1994, most recently as Associate Directory for Regulatory Affairs in the Division of Small Manufacturers Assistance and as Assistant Director for Reclassification and Compliance in the Office of Device Evaluation. The objections to this witness’s qualifications are overruled.⁶

Opinions 1 through 4 (that latex glove manufacturers and distributors were subject to statutory and regulatory obligations to inform healthcare workers of the risks of glove use, including the giving of timely warnings of the dangers of Type I hypersensitivity reactions; that their claims as to hypoallergenicity were misleading; and that they had a duty to report incidents to the FDA showing the potential for serious injury or death arising

Section Chief of Biostatistics and Epidemiology in the Department of Community and Family Medicine at Dartmouth Medical School and Director of Cancer Etiology at Norris Cotton Cancer Center. No objection was made to the qualifications of these witnesses.

⁴The opinions challenged: (1) NRL glove exposure increases the risk of sensitization or allergy; (2) health care workers who wear NRL gloves are at an increased risk for sensitization or allergy; (3) powdered NRL gloves increase the risk of sensitization or allergy in comparison with non-powdered gloves; (4) the level of protein or allergen in an NRL glove is associated with the risk of sensitization or allergy; and (5) a dose-response relationship exists between latex glove use and the development of sensitization.

⁵This ruling also applies to defendants’ joint motion *in limine* to exclude Dr. Gershwin’s MDL expert report opinion 8 (“Each and every exposure to natural rubber latex gloves manufactured without procedures to reduce water extractable proteins and allergen untis to a low level contributes to sensitization”). Gershwin Report 2/7/01 at 4.

⁶No witnesses were presented in rebuttal of Mr. Kyper’s testimony.

from glove use) – motion denied. However, unless properly predicated under Fed. R. Civ. P. 703, the witness’s hearsay testimony as to ethical issues will be excluded as incompetent.

3. Lawrence J. Broutman, Sc.D. – Dr. Broutman is president of Bodycote Broutman, Inc., a materials testing firm, and is Research Professor in the Department of Metallurgical and Materials Engineering at the Illinois Institute of Technology, Chicago, Illinois. The objections to this witness’s qualifications are overruled.⁷

Opinions 1 through 3⁸ – motion denied.⁹

Edmund V. Ludwig, J.

⁷Defendants’ rebuttal witness was Donald R. Uhlmann, Ph.D., Professor of Materials Science and Engineering and of Optical Sciences at the University of Arizona, where he is also Director of the Arizona Materials Laboratory.

⁸The challenged opinions: (1) NRL gloves are defective if the manufacturer did not reduce the extractable proteins or allergens to the lowest technically and economically feasible level; (2) whether and, if so, when a reasonable manufacturer knew or should have known of the allergic response caused by gloves with extractable proteins or allergens and, accordingly, should have changed its manufacturing process; and (3) the extent to which, if any, protein levels in NRL gloves in excess of specified levels adversely affect barrier protection.

⁹Dr. Broutman’s testimony is admissible subject to the parties’ stipulation that he will not testify to “medical expert opinions,” including opinions as to “what levels of protein or allergens in a glove:” (1) “cause the glove to be capable of causing latex sensitization and/or allergy;” (2) cause sensitization or allergy in general; or (3) are safe or unsafe either in a glove or in general. Stipulation 4/9/02 at 1.